JUN - 6 2001

K010697

510(k) Summary

Prepared by: Axon Systems, Inc.
400-2200 Oser Ave.
Hauppauge, NY 11788

Telephone: 631 436 5112
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Contact Person: Howard Bailin

Date Summary Prepared: March 5, 2001

Name of Device: Unique Ambulatory EEG

Common Name: Ambulatory EEG

Classification: Electroencephalograph (per CFR 882.1400)

Predicate Devices: Nicolet Inc. Satellite 510(k): K971331

Description of Device:
The Unique Ambulatory EEG is small EEG system that can be worn by the patient to provide ambulatory recording. Unique contains 18 channels, 16 for unipolar or bipolar EEG and 2 additional channels for recording other physiological data such as SaO2, pulse, respiration, EMG, etc.

Unique is battery powered for safety and portability. The recording system can be set to record at the same time each day. Patients can mark an "event' by pressing a button. Data is automatically stored before and after the button press.

The Unique Ambulatory EEG interfaces to the Phoenix Digital EEG via an optically isolated RS232 serial link. The Phoenix display screens can be used to enter demographic data, EEG data acquired by Unique, and provide status of patient electrode impedances.

Data is stored on a PCMCIA hard disk. The patient can change the hard disk without any special tools. The stored data can be read on the Phoenix Digital EEG system.

Unique uses high performance amplifiers and digital signal processing are used to insure high quality recorded data. A/D conversion is performed in the preamplifier/headbox to minimize interference. The patient is connected to the headbox by means of electrodes leads or electrode cap.

Intended Use of the Device:
The Unique Ambulatory EEG is intended for use in the recording of ambulatory EEG tests. EEG testing is intended for use whenever it is necessary to measure and record the electrical activity of a patient's brain by attaching multiple electrodes on the scalp. The device can be used provide continuous, long-term EEG monitoring.

The patient population includes adults, children and infants.

Summary of Technological Characteristics Compared to Predicate Devices:
The Unique Ambulatory EEG acquires data in the same manner as the predicate devices.

Summary of Clinical Testing:
The Unique Ambulatory EEG was tested and compared with predicate devices. See enclosed sample printouts. The results indicated no difference in the quality of data.

Summary of Non Clinical Testing:
Electrical safety and EMI Tests were performed in accordance with the requirements of IEC601.1 with no adverse findings. Tests using signal generators as stationary inputs confirm frequency response characteristics within specifications. Additional laboratory tests confirm the Unique Ambulatory EEG meets or exceeds published specifications

Based upon the documentation stated above and the safety and effectiveness criteria of the design and development process, validated by testing and quality control procedures, we claim the device to be safe, effective and substantially equivalent to the predicate device noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

Mr. Howard Bailin
Chief Operating Officer
Axon Systems, Inc.
400-2200 Oser Avenue
Hauppauge, New York 11788

Re: K010697
Trade/Device Name: Unique Ambulatory EEG
Regulation Number: 882.1400
Regulatory Class: II
Product Code: GWQ
Dated: March 5, 2001
Received: March 8, 2001

Dear Mr. Bailin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K010697

Device Name: Unique Ambulatory EEG

Indications for use:

The Unique Ambulatory EEG is intended for use in the recording of ambulatory EEG tests and other physiological data such as SaO2, pulse, respiration, EMG, etc.

EEG testing is intended for use whenever it is necessary to measure and record the electrical activity of a patient's brain by attaching multiple electrodes on the scalp. The device can be used provide continuous, long-term EEG monitoring.

The patient population includes adults, children and infants

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010697

Prescription Use ✓ OR Over-The Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)